PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference BIOKL11PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2008/079632	International filing date *(day/month/year)* 10 October 2008 (10.10.2008)	Priority date *(day/month/year)* 10 October 2007 (10.10.2007)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant GLOBAL ORGANICS LLC		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 13 April 2010 (13.04.2010)
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* 08 JAN 2009

Applicant's or agent's file reference
BIOKL11PCT

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 08/79632	10 October 2008 (10.10.2008)	10 October 2007 (10.10.2007)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A01N 37/12 (2008.04)
USPC - 514/567

Applicant GLOBAL ORGANICS LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	30 December 2008 (30.12.2008)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 08/79632

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 3-13, and 15-20 lack an inventive step under PCT Article 33(3) as being obvious over US 2004/0081712 A1 to Hermansen et al. (hereinafter 'Hermansen') in further view of US 2007/0116832 A1 to Prakash et al. (hereinafter 'Prakash')

As per claim 1, Hermansen discloses a method of treating or preventing glycosylation (abstract) related conditions, comprising, administering to a human or animal an effective amount of an anti-glycosylation composition comprising a high potency sweetener composition (abstract, corresponding to stevioside), optionally comprising mineral extracts (para [0124]) wherein the amount is effective in reducing at least a portion of the glycosylation events in a human or animal (abstract). Hermansen does not explicitly disclose treating glycation related conditions, or the use of mogroside, which is another high potency sweetener. However, Prakash discloses the use of multiple high potency sweeteners, including stevioside and mogroside in compositions, which share common characteristics of low calories and high intensity sweetening ability (para [0029]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of treating glycosylation related conditions such as diabetes as taught by Hermansen with the compositions comprising stevioside or mogroside as taught by Prakash, through routine experimentation, for the purpose of providing a method of treating glycation related conditions with high potency sweetener variability. Prakash teaches that mogroside is structurally and functionally equivalent to many other sweeteners, including stevioside. Additionally, glycation related conditions are similar functionally to gylcation related conditions as glycation is just glycosylation without the assistance of enzymes. However, both processes result in advanced glycosylation end products which influence diabetes, hypertension and other conditions the same way. Therefore, it is well within the purview of one of ordinary skill in the art to substitute mogroside for stevioside to treat glycation related conditions based on the teachings of Hermansen and Prakash as discussed above.

As per claim 3, Hermansen as modified by Prakash disclose the method of Claim 1. Hermansen further discloses wherein the composition comprises a mogroside/mineral extract composition (abstract, para [0124]).

As per claim 4, Hermansen as modified by Prakash disclose the method of Claim 1. Hermansen further discloses wherein the composition comprises a mogroside composition (abstract, para [0124], corresponding to optionally including minerals).

As per claim 5, Hermansen as modified by Prakash disclose the method of Claim 1. Hermansen further discloses wherein the composition further comprises a foodstuff (para [0162]).

As per claim 6, Hermansen as modified by Prakash disclose the method of Claim 1. Hermansen further discloses wherein the composition further comprises a beverage (para [0162]).

As per claim 7, Hermansen as modified by Prakash disclose the method of Claim 1. Hermansen further discloses wherein the glycation-related conditions comprise diabetes or athersclorosis (para [0156]).

As per claim 8, Hermansen discloses an anti-glycosylation composition comprising a high potency sweetener (abstract, corresponding to stevioside), and a mineral extract composition (para [0124]). Hermansen does not explicitly disclose an anti-glycation composition comprising mogroside. However, Prakash discloses the use of multiple high potency sweeteners, including stevioside and mogroside in compositions, which share common characteristics of low calories and high intensity sweetening ability (para [0029]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the composition as taught by Hermansen with the compositions comprising stevioside or mogroside as taught by Prakash, through routine experimentation, for the purpose of providing a composition that treats glycation related conditions with high potency sweetener variability. Prakash teaches that mogroside is structurally and functionally equivalent to many other sweeteners, including stevioside. Additionally, glycation related conditions are similar functionally to gylcation related conditions as glycation is just glycosylation without the assistance of enzymes. However, both processes result in advanced glycosylation end products which influence diabetes, hypertension and other conditions the same way. Therefore, it is well within the purview of one of ordinary skill in the art to substitute mogroside for stevioside in a composition to treat glycosylation related conditions based on the teachings of Hermansen and Prakash as discussed above.

As per claim 9, Hermansen as modified by Prakash disclose the composition of claim 8. Hermansen further discloses wherein further comprising a foodstuff or beverage (para [0162]).

As per claim 10, Hermansen as modified by Prakash disclose the composition of claim 8. Hermansen further discloses whereinfurther comprising a sweetener composition (para [0124]).

----------See Continuation Sheet----------

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V.2 Citations and Explanations:

As per claim 11, Hermansen as modified by Prakash disclose the composition of claim 8 wherein the composition comprises mogroside. The limitation disclosing use or functionality of mogriside is inherent in the composition

As per claim 12, Hermansen as modified by Prakash disclose the composition of claim 8 wherein the composition comprises a mineral extract composition (para [0124]). The limitation disclosing use or functionality of mineral extract is inherent in the composition.

As per claim 13, Hermansen discloses a method of inhibiting glycosylation reactions (para [0136]) related conditions, comprising, administering to a human or animal an effective amount of an anti-glycosylation composition comprising a high potency sweetener composition (abstract, corresponding to stevioside), optionally comprising mineral extracts (para [0124]) wherein the amount is effective in reducing at least a portion of the glycosylation events in a human or animal (abstract). Hermansen does not explicitly disclose inhibiting glycation reactions, or the use of mogroside, which is another high potency sweetener. However, Prakash discloses the use of multiple high potency sweeteners, including stevioside and mogroside in compositions, which share common characteristics of low calories and high intensity sweetening ability (para [0029]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of inhibiting glycosylation reactions as taught by Hermansen with the compositions comprising stevioside or mogroside as taught by Prakash, through routine experimentation, for the purpose of providing a method of inhibiting glycosylation reactions having high potency sweetener variability. Prakash teaches that mogroside is structurally and functionally equivalent to many other sweeteners, including stevioside. Additionally, inhibiting glycosylation is similar functionally to gylcation as glycation is just glycosylation without the assistance of enzymes. However, both processes result in advanced glycosylation end products and have other similar metabolic pathways. Therefore, it is well within the purview of one of ordinary skill in the art to substitute mogroside for stevioside to inhibit glycation reactions based on the teachings of Hermansen and Prakash as discussed above.

As per claim 15, Hermansen as modified by Prakash disclose the method of claim 13. Hermansen further discloses wherein the composition comprises a mogroside (see claim 13 discussion for reason mogroside is subsituted for stevioside)/ mineral extract composition (para [0124]).

As per claim 16, Hermansen as modified by Prakash disclose the method of claim 13. Hermansen further discloses wherein the composition comprises a mogroside composition (para [0124], corresponding to other components being optional).

As per claim 17, Hermansen as modified by Prakash disclose the method of claim 13. Hermansen further discloses wherein the composition further comprises a foodstuff (para [0162]).

As per claim 18, Hermansen as modified by Prakash disclose the method of claim 13. Hermansen further discloses wherein the composition further comprises a beverage (para [0162]).

As per claim 19, Hermansen as modified by Prakash disclose the method of claim 13. Hermansen further discloses wherein the composition is provided in vivo to a human or animal (para [0177]).

As per claim 20, Hermansen as modified by Prakash disclose the method of claim 13. Hermansen further discloses wherein the composition is provided in vitro (para [0054]).

Claims 2 and 14 lack an inventive step under PCT Article 33(3) as being obvious over Hermansen in view of Prakash and further in view of US 2003/0108624 A1 to Kosbab

As per claim 2, Hermansen as modified by Prakash disclose the method of Claim 1. Neither Hermansen nore Prakash explicitly disclose wherein the composition comprises a mineral extract composition only. However, Kosbob discloses a method of treating glycation related diseases such as diabetes (para [0009]), comprising a mineral extract composition (para [0043]-[0050], corresponding to Formula ID). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of treating glycosylation related conditions such as diabetes as taught by Hermansen as modified by Prakash with the method of treating glycosylation related conditions as taught by Kosbab, through routine experimentation, for the purpose of providing a method of treating glycation related conditions using more simplified, one major component compositions.

As per claim 14, Hermansen as modified by Prakash disclose the method of Claim 13. Neither Hermansen nore Prakash explicitly disclose wherein the composition comprises a mineral extract composition. However, Kosbob discloses a method of inhibiting glycation (para [0509], Table 1, corresponding to controlling glycosylation), comprising a mineral extract composition (para [0043]-[0050], corresponding to Formula ID). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of inhibiting glycosylation as taught by Hermansen as modified by Prakash with the method of inhibiting glycosylation as taughty by Kosbob, through routine experimentation, for the purpose of providing a method of inhibiting glycation using more simplified, one major component compositions.

Claims 1-20 have industrial applicability as as defined by PCT Article 33(4) because the subject matter can be made or used in industry